NCI, DCP, Chemoprevention Branch Progress Report

Instructions for Completing Page 1: PROGRESS REPORT TITLE PAGE

GENERAL:	This progress report title page must accompany all reports.
Date of Report	The date the report is prepared for submission.
Period Covered	The reporting period (*i.e.*, 4/1/97 – 4/30/97, 4/1/97 – 9/30/97) presented in the report.
Protocol Number	The IRB approved protocol number for the study referenced.
IND Number	The number assigned by the FDA to the agent application (IND).
Institutions	All institutions at which subjects may be or have been enrolled.
Prepared by	Individual responsible for preparing this report including title, address and telephone number.

Progress Report:

[Insert NCI Contract No. and Protocol Title]

Date of Report:

Period Covered:

Principal Investigator:

Principal Co-Investigator(s):

Protocol Number:

IND Number:

Institution(s):

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Instructions for Completing Page 2: SUMMARY OF PROGRESS

GENERAL:	This progress report summary page must accompany all reports.
Study Purpose	A one sentence description of the study including patient population (*i.e.*, title of protocol)
Study Population	Subject population under study
Treatment Groups and Duration of Drug Exposure	A brief description of all treatment groups and the duration of study drug (active and/or placebo) exposure
Study Completion Status	Status may be: screening – reviewing subjects for inclusion in study; ongoing – subjects are receiving the study drug(s) or in a run-in period; completed – last subject has completed treatment and all data has been collected
Number of Subjects Planned	Total number of subjects initially planned for inclusion
Current Enrollment	This section should include a breakdown of subjects entered by category. <u>In all cases, provide information for the current reporting period, as well as cumulative information for the study</u>.
Number Screened	Number of subjects that have been registered and/or evaluated for admission to the protocol. If an invasive protocol procedure (*i.e.* blood draw) is performed to determine eligibility, an informed consent must be signed.
Total Number Enrolled	Number of subjects that meet eligibility criteria and have given consent to participate in the study. A further breakdown of these subjects is as follows: Number on Run-In (if applicable) – Number of subjects in the run-in period. Run-in is usually a period for determining if subjects will be compliant with the dosing regimen. Adverse event information must be recorded during this run-in period. Number Randomized –Number of subjects randomized per protocol. Randomization is usually generated statistically to balance the treatment groups and allow sufficient statistical power. Subjects randomized are broken down into the following categories:

Currently Receiving Treatment – Number of subjects receiving the study drug(s) as of the reporting period.

Completed Treatment – Number of subjects that have completed receiving the study drug(s) as of the reporting period (normal completion).

On Follow-up (if applicable) – Number of subjects that are in the follow-up period as of the reporting period. Follow-up is usually a period after treatment in which the subjects are observed for safety. Based on the specifics of the protocol, adverse event information may need to be recorded during the follow-up period.

Number Completed Study – Number of subjects that terminated the study normally as per protocol.

Number Dropped Out (Total) – Number of subjects that terminated the study early. Break the total number down into the following categories:

Non-study Related – The subject dropped out due to any reason other than an adverse event (*i.e.*, lost to follow-up, personal reason, moved, *etc.*)

Adverse Event Related – The subject dropped out due to a toxicity, sign or symptom which may or may not be related to the study drug(s).

Total Number of Deaths

Total number of subjects that died during the study period including follow-up. Death is considered a SAE and should be reported to the NCI in two ways: through the Chemoprevention Branch SAE Form and the AE tables. Deaths should be further broken down into the following categories:

Related to Drug Administration – The death may have been related to the administration of the study drug(s).

Unrelated to Drug Administration – The subject's death was not related to the administration of the study drug(s) in the investigator's opinion.

Number of Subjects Replaced (if applicable)	The total number of drop outs that were replaced per protocol.
Number of Fully Evaluable Subjects	The total number of subjects that will be considered for statistical analysis in the opinion of the investigator. A definition of 'evaluable' should be included in the Statistical Analysis section of the protocol.
Description of Study Results to Date:	A summary of study results or interim results (when available) for the reporting period.
Action, Dose-Response, and Drug Bioavailability Data	A summary of data regarding the actions, dose response, and bio-availability of the drug(s) (when available) for the reporting period.
Protocol Revisions	A cumulative listing of protocol amendments that have been approved by the IRB including the relevant protocol amendment date (*i.e.,* Protocol Amendment 1, dated 1/15/97)
Informed Consent Revisions	A cumulative listing of informed consent revisions that have been approved by the IRB including the relevant informed consent date (*i.e.,* Informed Consent revision dated 1/15/97)

Progress Report: [Insert NCI Contract No. and Protocol Title]

Study Purpose:

Study Population:

Treatment Groups and Duration of Drug Exposure:

Study Completion Status:

Number of Subjects Planned:

Current Enrollment:

	Report Period		Cumulative		For CRA Use Only
Enrollment Category	**Subtotal**	**Total**	**Subtotal**	**Total**	
Number Screened					
Number on Run-in (if applicable)					
Number Randomized[1]					
Currently Receiving Treatment					
Completed Treatment					
On Follow-up (if applicable)					
Number Completed Study					
Number Dropped Out[2]					
Non-study Related					
Adverse Event Related					
Number of Deaths[3]					
Related to Drug Administration					
Unrelated to Drug Administration					
Number of Subjects Replaced (if applicable)					
Number of Fully Evaluable Subjects					

1 The subtotal numbers for the categories Currently Receiving Treatment, Completed Treatment and On Follow-up should add up to the Number Randomized total.

2 The subtotal numbers for the categories Non-study Related and Adverse Event Related should add up to the Number Dropped Out total.

3 The subtotal numbers for the categories Related to Drug Administration and Unrelated to Drug Administration should add up to the Number of Deaths total.

Description of Study Results to Date:

Actions, Dose-Response, and Drug Bioavailability Data:

Protocol Revisions:

Informed Consent Revisions:

Instructions for Completing Table 1: CUMULATIVE ACCRUAL DATA

GENERAL:	Update this table on a monthly or quarterly basis
Subject ID and Initials	The study number for the subject (not their hospital record number) and their initials.
Date of Birth	Use consistent numbering (*e.g.*, month/day/year).
Gender	Either M for male or F for female.
Weight	Include units (*e.g.*, lbs. or kg).
BSA	Body Surface Area if applicable. Define any calculations used to obtain m^2.
Height	Specify units (*e.g.*, cm or inches).
Study Drug Dose	Include dosage, units and frequency (*e.g.*, 200 mg bid).
Date Enrolled	Date (month/day/year) subject enrolled into study.
Date Study Drug Started And Stopped	Dates (month/day/year) subject received first and last dose on study.
Current Study Status	Subject status at the end of reporting period (i.e., off study, dropped out, ongoing).
Reason Off Study	If subject is off study, specify reason (*i.e.*, completed, dropout due to agent-related adverse event, dropout due to non-agent related reasons, poor compliance, personal reason, *etc.*)

Instructions for Completing Table 2: LISTING OF ADVERSE EVENTS

GENERAL:	Update this table on a monthly or quarterly basis. If information is unavailable, please use --- (dashes) for that particular box.
Subject ID and Initials	The study number for the subject (not their hospital record number) and their initials.
Dose at Event/ Randomized Treatment	The dose of the study drug the subject was receiving at the time of the event. The unit (*e.g.*, mg) and frequency (*e.g.*, bid) may be specified within the parentheses in the column header or within the table. If the study is a blinded study, provide the group number to which the subject was randomized (*i.e.*, Group A). If the subject experienced the adverse event during protocol run-in, use the code "PR". If the subject experienced the adverse event during follow-up, use the code "FU".
Duration of Drug at Event	The number of days the subject received the study drug before experiencing the event.
Event	Describe the event (*e.g.*, nausea, headache, pain in hands, *etc*.) Do not combine several events unless the events are clearly a syndrome (*e.g.*, cold, flu).
Grade	Determine from the NCI Common Toxicity Criteria. For events not covered by the NCI Common Toxicity Criteria or the protocol, use a numerical description (*i.e.*, mild (causing no limitation of usual activities) = 1; moderate (causing some limitations of usual activities) = 2; severe (causing inability to carry out usual activities) = 3; life-threatening = 4; fatal = 5.)
Event Start and Stop Date	Specify dates in month/day/year format.
Event Recovery Status	Indicate whether resolved or not resolved.
Relation to Drug	This is the Principal Investigator's assessment of the relationship between the event and the study drug. The following terms should be used: None, Unlikely, Possible, Probable, or Definite.

Drop Out Event Related	Specify whether the subject dropped out of the study due to an adverse event (Y for Yes or N for No).
Is this a SAE?	Indicate if a the adverse event qualifies as a Serious Adverse Event (SAE) reportable to the NCI, Chemoprevention Branch. ICH Guideline E6 defines a SAE as an adverse drug experience, occurring at any dose, that is any of the following: • fatal; • immediately life threatening; • results in inpatient hospitalization or prolongation of existing hospitalization; • results in persistent or significant disability/incapacity; or • results in a congenital anomaly/birth defect An NCI, Chemoprevention Branch Serious Adverse Event Form must be filed for an event tha is serious as defined by ICH Guideline E6 or which the investigator considers very unusual and/or potentially serious.